UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,914	02/14/2002	Chandru Chandrasekaran	01-462	1739

27774 7590 08/10/2005

MAYER, FORTKORT & WILLIAMS, PC
251 NORTH AVENUE WEST
2ND FLOOR
WESTFIELD, NJ 07090

EXAMINER	
WEBB, SARAH K	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/075,914
Filing Date: February 14, 2002
Appellant(s): CHANDRASEKARAN, CHANDRU

David Bonham
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4/29/05.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed

that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows:

In light of the arguments provided by applicant in the appeal brief, the 112 rejection of claims 14 and 16 has been withdrawn.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-10,13,14,18,20-22,25, and 27 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

Appellant's brief includes a statement that claims 1,5-10, and 12-14 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

Appellant's brief includes a statement that claims 2 and 11 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

Appellant's brief includes a statement that claims 14,16,17,19,23,24, and 26 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,824,049	Ragheb et al.	10-1998
5,725,567	Wolff et al.	3-1998
5,630,840	Mayer	5-1997

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

a. Claims 1-10, 13,15,18,2-22, 25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,824,049 to Ragheb et al.

Ragheb discloses a stent that can be adapted for endovascular, coronary, biliary, urinary, and tracheal purposes (abstract, line 3). The stent includes a metallic component in the form of an interconnected network of segments, as shown in Figure 7. Ragheb explains that the structure can be in the form of helix (column 6, line 46). The material of the metallic component (14) can be nitinol (column 7, line 35), as well as stainless steel and tantalum. Regarding claim 27, Ragheb explains that the surface of the metallic component (14) can be passivated (column 14, lines 50-55).

The stent base (14) is laminated between multiple layers of biodegradable polymers, as shown in Figures 1-5. Some biodegradable polymers that can be used for layers are polylactic acid, polycaprolactone, and polyglycolic acid (column 11, line 65 through column 12, line 1). The different layers can be formed from different polymers, as this gives the layers different degradation rates (column 13, lines 23-24).

b. Claims 1, 5-10, 12,13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,725,567 to Wolff et al.

Wolff discloses a stent (10) that includes a metallic component and a biodegradable polymeric material covering the metallic component. The metallic component (22) of the stent can be either braided (Figure 1) or formed as interconnected segments (Figure 2). Both structures have a plurality of apertures. Figures 4 and 14 more clearly illustrate the polymeric coating layers (14) disposed over the metallic filaments (22 or 16, respectively). The embodiment of the braided strands in Figure 14 shows that the polymeric material (18) provides support for the filaments (12), in that "the bonding at the juncture prevents the individual filaments from sliding relative to each other, which improves radial strength" (column 7, lines 20-22). Wolff explains that the polymer layer (14) is biodegradable and carries drugs (column 6, lines 45-46). The polymer material can be polylactic acid/polyglycolic acid (column 7, line 46), which meets the limitations of claim 5. The drugs contained in the polymer layer can be antiplatelet or anticoagulant (column 5), which are therapeutic.

Wolff explains that the stent can be endovascular, biliary, tracheal, etc. (column 1, lines 55-62). The stent can be either self-expandable or balloon expandable (column 9, line 66 through column 10, line 2).

The limitations of claim 12 only pertain to the process by which the patterned sheet is formed, so this is considered to be a product by process claim. Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. Therefore, the limitations of claim 12 were not given patentable weight.

c. Claims 2 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff in view of US Patent No. 5,630,840 (Mayer).

Wolff includes all the limitations of claim 11, except for the filaments comprising more than one metal. Mayer discloses a self-expanding braided stent (16) in Figure 1 that is similar to the structure of the Wolff braided stent. Mayer explains that in Figure 4 the core (24) is made of a radiopaque material, and the case (26) is made of a highly resilient material (column 6, lines 1-16). As shown in Figures 13 and 14, the filaments (80,88) can have three layers of different metals. Mayer teaches that it is desirable for stents to be both mechanical stable and highly radiopaque for imaging (column 2, lines 24-30). Mayer also teaches that titanium, tantalum, and cobalt alloys and stainless steel are suitable for the stent material (column 3, line 61-column 4, line 14). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the filaments of the Wolff stent from two different metals, as Mayer teaches that such a combination can provide a stent that is both mechanically stable and visible under fluoroscopy or x-rays.

d. Claims 14,16, 17,19, 23,24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragheb in view of Wolff.

Ragheb includes layers of therapeutic agents, which are listed from column 8 to column 10. Ragheb states that separate layers can include different therapeutic agents, and this allows the stent to perform more functions (column 13, lines 8-16). Ragheb also states that layers of different polymers can give bioactive agents different release rates (column 13, lines 23-24). Ragheb explains that a single layer can include two different therapeutic agents, because it is sometimes desirable to deliver two agents to tissue at the same time (column 16, lines 15-25).

Ragheb includes all the limitations of claims 14,16,17,19, 23, 24, and 26, but includes the therapeutic agent as a separate layer from the polymer layer. Wolff and Ragheb form the polymer layer from similar materials (PLA and PGA), and they are both intended for controlled release of therapeutic agents. Wolff teaches these polymers can carry therapeutic agents for controlled release of the drug (column 7, lines 40-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the therapeutic agent and polymer layers of Ragheb into one layer, as taught by Wolff, as this is simply an alternate way to accomplish controlled release of a drug by a polymer layer of a stent.

(11) Response to Argument

Applicant's arguments filed 4/29/05 regarding the 102 and 103 rejections have been fully considered but they are not persuasive. Applicant argues that the Ragheb and Wolff stents do not meet the limitations of claim 1, in that the metallic

components are not insufficient to maintain patency of a lumen in the absence of the polymer.

Whether a metallic structure can maintain patency of a lumen depends on many factors, including the size and shape of the lumen into which it is implanted. For example, if a the stent is implanted into a lumen with a larger diameter than the outer diameter the stent, the stent obviously will not be capable of maintaining patency in the passageway. Also, the phrase *"maintaining patency"* has several different interpretations in the art. Patency can be maintained by a stent structure exerting forces on the lumen wall to prevent collapse of the structure. Alternately, patency can be maintained by preventing endothelial cell growth or accumulation of debris in the lumen.

Either way "maintaining patency" is interpreted, it is well known in the art for restenosis to occur after implantation of a stent. As explained in lines 18-37 of Ragheb '049, it is well known in the art for a vessel to become occluded at the site of a stent implantation, even though the device was intended to prevent these complications.

Therefore, Examiner considers any prior art stent to be *insufficient to maintain patency of a lumen.* The prior art stent frames could damage the vessel wall to cause complications or be of an insufficient size to maintain optimum shape of the lumen. After the polymeric cover has degraded, the stent material would be incapable of preventing cell growth or accumulation of debris.

The specification nor the claims provide specific structural limitations that distinguish the claimed invention from the prior art used in the rejections. There are no specific amounts, ratios, or dimensions provided for any of the stent materials that

distinguish the claimed invention from prior art stents. Therefore, the Ragheb and Wolff stents are considered to meet the structural requirements of the claims, as they have a metallic component that is insufficient to maintain patency of a lumen and a biodegradable polymeric cover.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Sarah Webb SKW
8/2/2005

Conferees
Anhtuan Nguyen
Angela Sykes

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

MAYER, FORTKORT & WILLIAMS, PC
251 NORTH AVENUE WEST
2ND FLOOR
WESTFIELD, NJ 07090